

**Tennessee Medical Laboratory Board
October 19, 2017
Minutes**

Meeting Date: October 19, 2017

Time: 9:00 AM CDT

Location: Tennessee Department of Health
Division of Health Licensure and Regulations
Metro Center Complex, Iris Room, Ground Floor
665 Mainstream Drive
Nashville, TN 37243

Members Present:

Patti J. Walton, MT-Hospital/Lab Manager/Adm. Dir., Chair
Keisha Burnett, S.A.-Cytotechnologist
Mark A. Calarco, DO, Independent Lab Manager/Administrator
Tereyo M. Cox, MT-Medical-Technologist, General
Carla M. Davis, MD-Pathologist
Jason S. Nolan, MD-Pathologist, Non-Educator
Jon Parham, DO Non-Pathologist Physician
Stephanie Dolsen, MT Supervisor Vice-Chair
Gaye G. Jolly, MT-Hospital Administrator
Kathleen Kenwright, MT- Medical Technologist, Educator

Members Absent:

Michael Johnson, MT-Medical Technologist Generalist
Royce Joyner, MD-Pathologist Educator
Michael J. Wright-Citizen Representative

Vacant Position: All board positions filled.

Staff Absent: All staff present for the meeting.

CLIA Manager/Representative: Sandra Bogard, MT CLIA Manager

Presiding Officer: Patti Walton, MT, Chair

Call To Order: The meeting was called to order at 9:04 am CDT by Board Chair Patti J. Walton.

Introduction of Board Members: Board members and staff made their introductions to the record.

Introductions of Staff: Board members and staff made their introductions to the record.

Quorum: Ten board members were present which constitute a quorum.

Approve Minutes

P & E Committee Meeting

A motion to approve the July 20, 2017 Personnel & Education Committee minutes was made by Ms. Kenwright.
Second: Ms. Dolsen
Committee Minutes: Approved

Full Board Meeting

A motion to approve the July 21, 2017 board meeting minutes was made by Ms. Jolly.
Second: Dr. Davis
Board Minutes: Approved

Board Reports:

Ratification of Initial Determinations of the P&E Committee Meeting:

Ms. Kenwright reported the actions of the Personnel & Education Committee meeting, October 18, 2017.

Motion to ratify Committee actions: Dr. Calarco
Second: Ms. Jolly
Report: Accepted as presented

Consent, Agreed, Compliance Orders & Letters of Reprimand

Consent Orders

No consent orders were presented.

Agreed Orders

No Agreed Orders presented.

Compliance Orders

No Compliance Orders presented.

Letters of Reprimand

No Letters of Reprimand were presented.

Presentations to the Board:

Tennessee Professional Peer Assistance Program (TnPAP):

Mr. Mike Harkreader, MS,RN,CARN
TnPAP Director

The statistical report for July 1, 2017-September 30, 2017 was presented with two (2) individuals monitored during this time period.

One individual was referred for a substance abuse disorder while the other individual was referred for other treatment source.

TnPAP evaluations were performed with both individuals; one individual has an agreement pending with this agency.

Motion to accept the TnPAP report: Ms. Dolsen
Second: Ms. Cox
Report accepted as given.

Note: Review of TnPAP materials via internet counts as clock hours toward continuing education credits.

A certificate of completion documenting review of these materials can be completed at the end of the session. Internet site: www.TNPAP.org

**Financial Report
Noranda M. French
Presentation/Discussion**

Ms. French gave the Mid-Year financial report during the meeting. Expenditures for the year-end FY17 year.

Revenue values for this profession were presented in detail, broken down into each category.

The total expenditures for 2017 were \$521,822.89, with the cumulative carryover \$1,712,415.61.

Board members were asked to consider a possible reduction in all fees for personnel, training programs, and facilities based on the carryover data.

After discussion, board members decided to wait before a decision to lower fees based on additional review with Ms. French and Ms. England.

Motion to accept the report: Dr. Parham
Second: Dr. Nolan
Report accepted as given.

A copy of the report is on file in the administrative office.

**Investigations Report
Dorsey Luther
Disciplinary Coordinator**

December 2016-July 2017

Personnel: No complaints were made to the investigative unit from July until October. One complaint was closed in August with an accompanying letter of warning.

Currently one open complaint is in a monitoring status.

Facilities: No complaints received in investigations from July until October.

Motion To Accept Report: Ms. Kenwright
Second: Dr. Parham

The investigations report was accepted as given by Ms. Luther.

**Legislative Report
DOH Commissioner's Office
Legislative Liaison
Legislative Affairs
James Layman**

No report was given during the meeting because legislative actions effecting the practice of laboratory medicine were not promulgated during the past quarter.

Discuss, review, take action, if needed, regarding but not limited to:

Ratifications:

**The following items were presented to board members for ratification per staff, state surveyor or facility request:
Necessity of Licensure**

Ms. England presented a document for board review concerning the necessity of continuing the renewal of a facility that currently possesses a Tennessee laboratory license if anatomic/clinical laboratory testing procedures were not currently performed in that physical location.

All licenses granted by the board are with the intent of full compliance with statute Tennessee Code Annotated §68-29-101, and the rules and regulations promulgated by the board for medical laboratory operations.

However circumstances may arise which can produce a delay in the services and analyses of specimens, especially in the newer area of emerging technologies relative to the actual processing of clinical samples for prognosis, diagnosis or

treatment of an individual.

After discussion board members decided it was the holder of the laboratory license who makes the business decision of whether to voluntarily relinquish the license or to continue the annual renewal process.

No vote was taken as this subject was for administrative clarification for board staff and surveyors.

Ratifications:

The following items were presented for ratification per staff, state surveyor, or facility request:

**Point of Care Exemptions
1200-06-03-.16(1)**

**1.Saint Francis Hospital
5959 Park Avenue
Memphis, TN 38119
Cathy Crews
Doretha Franklin**

This exemption request was for Registered Nurses (RN's) to perform and report activated clotting time (ACT's) in the Interventional Radiology Department utilizing the Hemochron analyzer.

Motion: Ms. Jolly
Second: Dr. Calarco

Exemption granted

**2.Erlanger Medical Center
975 East Third Street
Chattanooga, TN 37043**

This facility request was for the following exemptions for the Children's Hospital Emergency Room point of care:

1-to permit Registered Nurses (RN's), Licensed Practical Nurses (LPN's) and Paramedics to perform and report Flu A & B testing procedures utilizing the BD Veritor System.

Motion: Dr. Calarco
Second: Ms. Dolsen

Exemption: Approved

2-to permit Registered Nurses (RN's), Licensed Practical Nurses (LPN's), and Paramedics to perform and report Group A Streptococcus values utilizing the BD Veritor System.

Motion: Ms. Dolsen
Second: Ms. Jolly

Exemption: Approved

3-to permit Registered Nurses (RN's), Licensed Practical Nurses (LPN's), and Paramedics to perform and report RSV values utilizing BD Veritor System.

Motion: Dr. Calarco

Second: Ms. Jolly

Exemption: Approved

Two other exemptions were requested for the Special Pathogens Unit:

1-to add Paramedics to a previously granted exemption (October, 2016) for WBC testing utilizing the Hemocue.

Motion: Dr. Calarco

Second: Dr. Davis

Exemption: Approved

2-to add Paramedics to a previously granted exemption (April 2017) for malaria testing procedures utilizing the BinaxNOW Malaria Test Kit.

Motion: Dr. Calarco

Second: Dr. Nolan

Exemption: Approved

Direct 3+ Labs
1200-06-03-.13(5)

No requests were presented during this meeting.

Reports/Requests:

Board Director's Report
Lynda S. England BS MT(ASCP)

Ms. England gave the board director's report for the quarter July 01, 2017 thru September 30, 2017.

The report included statistical data concerning the licensure of laboratory personnel, laboratory facilities and health fair/health screening events.

Motion: Ms. Kenwright
Second: Dr. Parham

After review and discussion board members accepted the report as given.

(A copy of the report is kept on file in the board's administrative office)

**Board Attorney Report
Kyonté Hughes-Toombs
Deputy General Counsel**

Counsel Hughes-Toombs gave her report for the past quarter:

There were no cases for review in investigations and the re-write of the Rules Governing Medical Laboratory Personnel 1200-06-01 are still under review.

Motion: Ms. Jolly
Second: Dr. Davis

Report approved as given.

REINSTATEMENT OF LICENSE

No licenses to reinstate this quarter.

ADDITIONS/DELETIONS TO THE BOARD'S WAIVED TEST LIST

**TDH HIV/AIDS Section
Nashville, TN 37243-1219
Carolyn Wester, MD
Medical Director**

This request was for the addition of two (2) testing procedures to be added to the waived test list for this Division to remain in authority of who and where the screenings would be performed; limited to HIV/AIDS Division only.

1) ChemBio DPP HIV 1/2 Antibody Test

This test utilizes oral fluid, whole blood or venous blood specimens with results in thirty minutes (oral fluid) and fifteen minutes for blood samples.

The test would serve as confirmatory for preliminary reactive result when using the previously approved Orasure OraQuick Rapid HIV screening test.

Motion: Dr. Davis
Second: Dr. Nolan

Request approved

2) Biolytical INSTI Rapid HIV Antibody Test

This test utilizes finger stick blood samples and provides results in one minute and is to be utilized as a confirmatory test for a preliminary reactive result when using the Orasure OraQuick Rapid HIV screening test.

Adding these tests to the menu for this division would allow greater access to hard to reach populations at high risk for HIV and provide results confirmation in a quicker turnaround time..

Motion: Dr. Davis
Second: Dr. Parham

Request approved

Licensure of Medical Laboratory Director

1) Chenbo Dong, Ph.D. Little Rock, AR 72205

Dr. Dong received his BS degree from Beijing University, China in 2007 in Chemical Engineering, his Master's degree from the China University of Petroleum in 2010 in Chemical Engineering.

He obtained his Ph.D. from the West Virginia University, Morgantown, WV in Chemical Engineering.

Work experience was obtained from Walker Toxicology Labs, LLC in Birmingham, AL and Pathology Partners in Little Rock, AL. In both work experiences Dr. Dong performed enzyme immunoassay (EIA) and LCMS confirmation technique for pain clinics.

Dr. Dong is currently certified by the National Registry of

Certified Chemists as a Clinical Chemist and seeks licensure in Tennessee as a Director of Chemistry.

Motion to approve: Ms. Kenwright

Second: Dr. Calarco

Director license granted.

2) Jennifer McKenzie, Ph.D.
Antioch, TN 37013

Dr. McKenzie received her BA from Hendrix College in Conway AR in Chemistry with her Ph.D. from Vanderbilt University, Nashville, TN in Chemistry.

She is currently certified by the National Registry of Certified Chemists as a Toxicological Chemist and received her training experience at Insight Diagnostics Toxicology Laboratory in Franklin, TN.

Dr. McKenzie seeks licensure as a Director of Toxicology.

Motion: Ms. Dolsen

Second: Dr. Calarco

License approved.

**Regional Surveyors Reports,
Complaint Investigations/PT
Events
Regional Offices:
East, Middle, West Tennessee**

**ETRO Report
Taylor Carpenter, MT
Consultant/Surveyor**

East TN Regional Office: July 01-September 30, 2017

Complaint Investigations: Zero

Unsuccessful Proficiency Testing:

One first unsuccessful PT event for total protein with an acceptable plan of correction provided to the surveyor.

**MTRO Report
Richard Carroll, MT
Consultant/Surveyor**

Middle TN Regional Office: July 01-September 30, 2017

Complaint Investigations: One
Unsuccessful Proficiency Testing:

Two facilities were reported with a first unsuccessful PT.
2nd Unsuccessful PT Event: Zero

WTRO Report
Karon Hathcoat, MT
Consultant/Surveyor

West TN Regional Office: July 01-September 30, 2017

Complaint Investigations: Zero

First Unsuccessful Proficiency Testing : Four
Second Unsuccessful Proficiency Testing: One

Motion to accept regional surveyor reports: Ms. Dolsen
Second: Ms. Cox

All surveyor reports accepted as presented.

Board Ratifications
Facility Laboratory Applications

Quest Diagnostics Kingsport
2004 American Way Suite 113
Kingsport, TN 37660

Specialties: Collection Station

Laboratory Director: Kristin Pierce, M.D.
Anatomic/Clinical Pathology

Motion: Ms. Kenwright
Second: Ms. Cox

License Approved.

Quest Diagnostics Knoxville
10235 Cogdill Road Suite 204
Knoxville, TN 37932

Specialties: Collection Station

Laboratory Director: William Konomos, M.D.
Anatomic/Clinical Pathology

Motion: Ms. Kenwright
Second: Dr. Parham

License Approved.

**University of Tennessee
Pathology Laboratory, LLC
930 Madison Ave Suite 545A
Memphis, TN 38103**

Specialties:
General Immunology, Histopathology, Oral
Pathology, and Cytopathology

Laboratory Director: Abdallah Azouz, M.D.
Anatomic/Clinical Pathology
Hematological Pathology

Motion: Ms. Dolsen
Second: Dr. Davis

Licensed Approved.

**Clinical Pharmacokinetics Lab-E
St. Jude Children's Research
262 Danny Thomas Place
Mail Stop 313 Room I-5501
Memphis, TN 38105**

Specialties: Esoteric Toxicology

Laboratory Director: Alejandro Molinelli, Ph.D.
Director: Chemistry

Motion: Dr. Calarco
Second: Ms. Dolsen

License Approved.

**Quest Diagnostics-Chattanooga
5959 Shallowford Rd. Suite 427
Chattanooga, TN 37421**

Specialties: Collection Station

Laboratory Director: Phillip Pollock, M.D.
Anatomic and Clinical Pathology

Motion: Ms. Kenwright
Second: Ms. Jolly

License Approved.

**BMHSI-AEL Microbiology Lab
1701 Century Center Cove #200
Memphis, TN 38134-8975**

Specialties: Bacteriology and Mycology

Laboratory Director: Michael Bugg, M.D.
Anatomic/Clinical Pathology

Motion: Ms. Jolly
Second: Ms. Cox

License Approved.

Ms. Dolsen abstained from discussion and vote.

**Compass Laboratory Service
Esoteric Section
1910 Nonconnah Blvd. #108
Memphis, TN 38132**

Specialties: Esoteric Toxicology

Laboratory Director: Charles R. Handorf, M.D.
Anatomic/Clinical Pathology

Motion: Ms. Jolly
Second: Dr. Davis

License Approved.

Specialties: Virology, Hematology, General Immunology,
ABO Group & Rh Type, Antibody Detection
(Transfusion), Antibody Detection (Non-
transfusion), Compatibility Testing,
Clinical Chemistry, Urinalysis, Endocrinology,
Toxicology, Blood Gas + pH, KOH, Wet Prep,
Strep A Antigen Screen, Waived Glucose.

Laboratory Director: Courtney Hanna, M.D.
Anatomic/Clinical Pathology

Motion: Ms. Jolly
Second: Dr. Parham

License Approved.

Discussion

Ms. England requested board clarification pertaining to an application submitted to the administrative office.

The application is for a Tennessee facility licensure performing esoteric toxicology techniques.

Following the submission of the application, additional information (non-licensed esoteric testing employees) would be working out of state as well as in state per T.C.A, 68-29-138 but not within the physical laboratory location but from their home environment.

After discussion board members decided the application was to be honored with an on-site initial inspection of the laboratory resulting in board review of both 1) esoteric laboratory licensure and 2) employee-laboratory location relationships.

No action was taken on this matter, procedural clarification only.

Statement of Next Meeting

The next Board Meeting will be January 18, 2018 and is scheduled to begin at 9 AM CST in the Iris Conference Room, Ground Floor, Metro Center Complex, 665 Mainstream Drive, Nashville, TN 37243

Record of Adjournment

With no further business to discuss and with a motion properly presented, the meeting adjourned at 12:52 pm CDT.

Motion to adjourn: Ms. Kenwright
Second: Dr. Parham

Meeting Adjourned.
